No. 1:17-md-02775

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Baltimore Division)

IN RE SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL THA-TRACK AND R3-TRACK CASES

DEFENDANT SMITH & NEPHEW, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO EXCLUDE THE OPINION TESTIMONY OF PLAINTIFFS' EXPERT WITNESS HAROLD PELLERITE

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INTRODUCTION & SUMMARY

Defendant Smith & Nephew, Inc. ("Smith & Nephew") respectfully submits this Memorandum in Support of its Motion to Exclude the Testimony of Plaintiffs' regulatory expert, Harold Pellerite, a retired FDA official and device consultant. Mr. Pellerite's opinions are inadmissible because they are relevant only to preempted claims, are not the product of reliable methods, are beyond his area of expertise, and are likely to confuse or mislead the jury and unfairly prejudice Smith & Nephew. *See* Fed. R. Evid. 702, Fed. R. Evid. 401-403.

First, many of Mr. Pellerite's opinions are inadmissible because they are relevant only to preempted claims and preempted theories of liability, including those the Court already has held are preempted in its THA preemption ruling. *See In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Implant Prods. Liab. Litig.*, 401 F. Supp. 3d 538, 551–54 (D. Md. 2019) ("*THA Preemption Ruling*"). In particular, Mr. Pellerite seeks to opine that: (1) the BHR cup and R3 metal liner at issue in this litigation (both PMA device components) were not legally marketed, (2) Smith & Nephew had a duty to train or warn surgeons or the public about an off-label use of an approved or cleared device, and (3) Smith & Nephew should have changed the labeling of the BHR cup or R3 metal liner, both of which are subject to the BHR's premarket approval by FDA. All of these opinions are expressly preempted because they would impose new or different obligations than the obligations the FDA has already imposed on these BHR components, and many of these opinions are impliedly preempted because they seek to arrogate to Plaintiffs the regulatory authority entrusted exclusively to the FDA.

Second, these opinions and others also are inadmissible because they are unreliable, beyond Mr. Pellerite's narrow area of expertise, and likely to confuse the jury or prejudice Smith & Nephew. Most notably, the crux of Mr. Pellerite's opinions in these cases is his improper and legally unsound conclusions that the BHR-THA and R3-THA are unapproved devices (a

conclusion the Court has rejected) and that evidence in the case demonstrates unlawful off-label promotion by Smith & Nephew. These conclusions, however, are inadmissible under Rule 702 because they would (1) invade the role of the Court to instruct the jury on the law, (2) usurp the role of the jury to apply the law to the facts in evidence, and (3) are fundamentally unsound and based on nothing more than *ipse dixit*. Lastly, Mr. Pellerite offers opinions based on irrelevant and confusing observations about foreign regulatory actions and his baseless speculation about what surgeons know or rely upon. None of these opinions meets the requirements of Rule 702 and 403.

Accordingly, Mr. Pellerite's opinions about these topics and those described in more detail below are inadmissible under Rule 702 and 403.

BACKGROUND

A. Overview of the Relevant Devices.

There are two FDA-approved or -cleared devices at issue in the THA/R3 Track of this multidistrict litigation: Smith & Nephew's Birmingham Hip Resurfacing ("BHR") system and the modular femoral head ("MFH"). Smith & Nephew's BHR is a premarket approved ("PMA") orthopedic device indicated for use in hip resurfacing. *See* Expert Report of David L. West ("West Rep.") (Ex. A) at 61–62, 67–68. The BHR device consists of two components: a metal acetabular cup for fixation to the acetabulum and a metal femoral head resurfacing component for fixation to the femoral head. *See id.* These components of the BHR received premarket approval on May 9, 2006. *See* BHR Premarket Approval Order (May 9, 2006) ("Premarket Approval Order") (Ex. B). Premarket approval reflects the FDA's judgment that, based on a multi-volume application and thousands of hours of review, there are reasonable assurances of the device's safety and effectiveness. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008); *In re Smith & Nephew Birminghman Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, *BHR,* 300 F. Supp. 3d 732,

745 (D. Md. 2018) ("*In re BHR I*") ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means."). As a condition of PMA, the FDA closely monitors and regulates the BHR's design, marketing, sale, labeling, and indications for use. *See id.* at 548–49; *see also* West Report (Ex. A) at 62–64.

In 2008, the FDA approved a line extension of the BHR PMA for a modular acetabular cup, consisting of an R3 acetabular shell and an R3 metal liner. *See* PMA Supplement No. 6 [SN_BHR_MDL-0013516] (Ex. C) at 2–7. As part of this PMA supplement, Smith & Nephew added labeling advising surgeons that the R3 metal liner was intended for use with the BHR system only, and that if a surgeon decides to convert from a resurfacing procedure to a total hip procedure (either during a resurfacing or as part of a revision surgery), the R3 metal liner would have to be removed. *See* R3 Modular Resurfacing Acetabular Cups—Surgical Technique Addendum [SN_BHR_MDL_2515991] (Ex. D) at 8, 10.[1]

Upon approval of the line extension, the R3 shell and liner became components of the BHR PMA device. As the Court has ruled, FDA's pre-market approval extends both to the device as a whole and to each individual component. *See THA Preemption Ruling*, 401 F. Supp. 3d at 551–54. Accordingly, the BHR acetabular cup, metal femoral resurfacing head, the R3 shell, and the R3 metal liner are all—as individual components and as a system—PMA approved by FDA. *See id.* at 552.

The second device at issue in this litigation is the Smith & Nephew modular femoral (hemi) head, or "MFH." In 2006, Smith & Nephew obtained clearance for the MFH under section 510(k) of the federal Food, Drug & Cosmetic Act ("FDCA"). The MFH is an artificial, cobalt-chrome

[1] Smith & Nephew voluntarily recalled the R3 metal liner in 2012. *See* West Report (Ex. A) at 71–72.

implant that replaces the natural (or a prior artificial) femoral head. The MFH connects with a femoral stem that is implanted in a patient's thigh bone. The MFH was cleared for use in hemi-hip arthroplasty, meaning a procedure where an artificial femoral head is implanted to articulate against the patient's natural acetabulum. West Report (Ex. A) at 67. In countries outside of the United States, the MFH was commercially available for use in total hip arthroplasty, meaning both the MFH and an acetabular cup are implanted. Deposition of Andrew Weymann (*McKanneny v. Smith & Nephew, Inc.*, No. 3:17-cv-00012 (D. Conn.) ("Weymann Dep.") (Ex. E) at 35–36.

In the THA and R3 tracks of this litigation, Plaintiffs allege to have been injured by their physicians' use of the MFH in combination with a BHR acetabular cup or R3 metal liner as part of a total hip arthroplasty procedure. Specifically, Plaintiffs' Master Amended Consolidated Complaint for Plaintiffs with BHR Cups, Modular Femoral Heads and Stems (Aug. 14, 2018) [D.E. 878] ("THA MACC") alleges that Plaintiffs each received a PMA-approved BHR acetabular cup, used in combination with a non-BHR MFH, modular neck sleeve, and femoral stem. THA MACC [D.E. 878] ¶ 116. Plaintiffs' Master Amended Consolidated Complaint for Plaintiffs with R3 Total Hip Cases (Sept. 21, 2018) [D.E. 966] ("R3 MACC") alleges Plaintiffs received R3 metal liner used in combination with a MFH and other non-BHR components as part of a total hip arthroplasty procedure. *See* R3 MACC [D.E. 966] ¶ 10.

These constructs, which Plaintiffs refer to as the BHR-THA and the R3-THA, respectively, *see THA Preemption Ruling*, 401 F. Supp. 3d at 547, were never approved as devices in the United States and Smith & Nephew has never marketed them as such. *See, e.g.*, West Report (Ex. A) at 75, 88–89. Rather, these constructs were chosen by each Plaintiff's physician as part of his or her practice of medicine. The FDA does not have authority to regulate the practice of medicine, and Congress has dictated that FDA lacks authority to dictate to physicians concerning decisions

pertaining to the use of a legally marketed medical device. *See, e.g.*, 21 U.S.C. § 396. The use of a device by a physician in a manner other than its approved or cleared indications is lawful and is referred to as "off-label" use. Indeed, the Supreme Court has explained that "'off-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

A manufacturer is not liable for the physician's off-label use. Further, responding to questions from physicians or providing components ordered by physicians does not constitute off-label promotion, again, provided the manufacturer does not suggest or encourage the off-label use or discuss the off-label use without prompting from the physician. *See, e.g.*. West Report (Ex. A) at 59–60. To ensure that manufacturers are not engaged in unsolicited off-label promotion, FDA regularly monitors print and web advertising and investigates credible allegations of off-label promotion. *Id.* at 57–58, 75. If the FDA identifies unlawful off-label promotion by a manufacturer, it can issue a Warning Letter requiring the manufacturer to take corrective action. *Id.* The FDA has never issued Smith & Nephew a warning letter concerning off-label promotion of the BHR, its components, or the MFH. *See* West Report (Ex. A) at 70–75 ("If FDA has found patterns of off-label promotion, the Agency undoubtedly would have issued a Warning Letter.").

B. The Court's THA Preemption Ruling.

On November 9, 2019, Smith & Nephew moved to dismiss Plaintiffs' THA-track and R3-track claims based upon express and implied preemption. [D.E. 1173]. Smith & Nephew highlighted that off-label use by surgeons of BHR components in a "hybrid" system of PMA-approved and 510k-approved components does not insulate Plaintiffs' claims from federal preemption. Rather, the express preemption provision of the MDA draws no distinction between

"on-label" and "off-label" uses, and Plaintiffs' claims impermissibly would impose requirements on BHR components that are in addition to and different from existing PMA requirements. *Id.* at 1-2; *see* 21 U.S.C. § 360k(a); *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1343-45 (10th Cir. 2015) ("§ 360k(a) simply does not contain the distinction . . . between suits addressing on-and off-label uses").

On August 5, 2019, this Court issued an Order and accompanying Memorandum granting in part and denying in part Smith & Nephew's Motion to Dismiss. *See* Order [D.E. 1704]; Memorandum [D.E. 1714] (corrected, Aug. 14, 2019). In its Memorandum, the Court recognized that "the BHR cup in the BHR-THA system and the R3 metal liner in the R3-THA system received PMA approval," but that other components used in those constructs "were approved through the § 510(k) process." *THA Preemption Ruling*, 401 F. Supp. 3d at 551. Under *Riegel*, PMA-approved devices and components thereof are subject to federal "requirements" relating to safety and effectiveness that preempt non-parallel state law claims, but devices and device components cleared through the § 510(k) process are not subject to such requirements. *See* 552 U.S. at 322–23. In its *THA Preemption Ruling*, the Court addressed whether "incorporation of a premarket-approved component" with § 510(k) cleared components "extends § 360k(a)'s preemption protection to all claims targeting the device." 401 F. Supp. 3d at 551–52.

Construing the MDA and competing case law on this topic, the Court adopted "a tripartite approach": "§ 360k(a) preempts non-parallel state-law claims that target pre-market approved components, but it does not govern state-law claims that target a hybrid system's § 510(k) components or the system as a whole." *Id.* at 555. Thus, "claims targeting hybrid systems, such as claims directed at the § 510(k) components of the system or claims that do not impose a new requirement on a premarket-approved component would not be preempted." *Id.* at 554 (citing

Shuker v. Smith & Nephew, PLC, 885 F.3d 760, 775 n.15 (3d Cir. 2018)). On the other hand, the Court explained that, if "the BHR cup or the R3 metal liner [is] 'at the heart' of the plaintiffs' claims" then it "may be that" "preemption will be required." *Id.* at 556 n.8.

Applying this framework, the Court concluded that the THA-track and R3-track Plaintiffs' claims are preempted to the extent they assert that Smith & Nephew:

(1) is strictly liable for design defects in or failure to warn regarding the BHR cup or the R3 metal liner; *THA Preemption Ruling,* 401 F. Supp. 3d at 556;

(2) breached any implied warranty as to the R3 metal liner, *id.*;

(3) negligently failed to warn "the public or the medical community" about adverse events associated with the BHR cup or R3 metal liner, *id.* at 557-58;

(4) should have amend the labeling of the BHR cup or R3 metal liner, *id.* at 562;

(5) should have recalled the BHR cup or R3 metal liner, *id.*; or

(6) had a duty to train surgeons as to the BHR-THA or R3-THA constructs, *id.* at 563.[2]

C. Mr. Pellerite's Experience and Opinions.

Plaintiffs have designated Harold Pellerite as a regulatory expert for the THA- and R3-Track cases in this multidistrict litigation. Mr. Pellerite is a medical device consultant and a retired FDA official. Expert Report of Harold Pellerite (Mar. 22, 2021) ("Pellerite Report") (Ex. F) at 1-2. Mr. Pellerite spent the majority of his years at FDA in the Office of Compliance. *Id.* at 1. The Office of Compliance is an enforcement arm of the FDA. West Report (Ex. A) at 47–49. The Office of Compliance is not involved in approving or clearing devices, nor is it the lead FDA office responsible for market surveillance; rather those responsibilities lie with the Office of Device

[2] Smith & Nephew moved under 28 U.S.C. § 1292(b) to certify the *THA Preemption Ruling* for interlocutory appeal to the Fourth Circuit. [D.E. 1772]. The Court denied certification on November 27, 2019. *See* Memorandum [D.E. 1951]; Order [D.E. 1952]. Smith & Nephew does not seek to relitigate the prior preemption ruling here, but respectfully reserves the issues presented in its prior motions for further appellate review.

Evaluation ("ODE"), which may request the Office of Compliance to conduct a site inspection or otherwise assist if ODE believes such actions are is warranted. *Id.* ODE performs all aspects of reviewing PMA applications and § 510(k) clearance notifications without any involvement from the Office of Compliance (unless ODE requests coordination). *Id.* Mr. Pellerite is not a lawyer or a medical doctor. Pellerite Report (Ex. F) at 1.

Mr. Pellerite bases his report on the misnomer that the BHR-THA[3] and R3-THA are "unapproved devices," rather than off-label constructs that utilize components of approved or cleared devices. *See id.* at 4–6. To reach this conclusion, Mr. Pellerite asserts that a device is considered to be approved or cleared "[o]nly when all of the components are used together," and that the "FDA did not clear or approve components" of the BHR. *Id.* at 5. The Court, however, has already held the exact opposite. Noting that the "MDA defines device to include 'component' parts," the Court concluded that BHR components are "premarket-approved component[s]," even when used in combination with non-PMA components. *See THA Preemption Ruling*, 401 F. Supp. 3d at 551–52; *see id.* at 552 ("Because the MDA defines device to include 'component' parts, courts have held that once a device as a whole receives PMA approval, the MDA preempts non-parallel state law claims directed at not only the device as a whole, but also at the device's component parts"). Moreover, Mr. Pellerite's interpretation of FDA law—one where every use is either approved or unapproved—would eliminate entirely the category of "off-label" uses of PMA components in hybrid device constructs. The MDA does not adopt such a restrictive approach; rather, it "implicitly encourages" physicians to use PMA devices and components thereof off-label,

[3] The terms "BHR-THA" and "R3-THA" are litigation terms created by Plaintiffs solely for and in this litigation, and do not reflect any actual device marketed by Smith & Nephew or recognized by any authority. By using those terms herein, Smith & Nephew does not mean to imply agreement or acceptance that they are an appropriate description of the THA constructs at issue.

including in combination with unapproved device components. *See id.* at 553–54. Therefore, contrary to Mr. Pellerite's assertions, federal law (as interpreted by this Court) confirms that the FDA has approved all components of the BHR (including the acetabular cup and the R3 metal liner) and cleared (via the 510k process) all of the components comprising the MFH.

Based on his mistaken view that the BHR components are unapproved outside of the BHR system, Mr. Pellerite offers three primary opinions. *First*, Mr. Pellerite opines that the BHR-THA and R3-THA were not off-label constructs of approved components but rather were unapproved devices because "FDA does not approve (clear) the individual components in either system." Pellerite Report (Ex. F) at 5. According to Mr. Pellerite, "for a use to be off label, the device in question must be legally marketed," and, therefore, "when the BHR cup was used in a THA it was an *unapproved use* and not an *off-label use*." *Id.* at 5–6. Mr. Pellerite then cites three surgeons who did not know, or did not recall whether they knew, that the BHR-THA and R3-THA were not approved constructs and opines that, as a reasonable device manufacturer, Smith & Nephew should have alerted surgeons to this fact. *See id.* at 6–8; Deposition of Harold Pellerite (Apr. 28, 2021) ("Pellerite Dep.") (Ex. G) at 158–59; *but see id.* (admitting a manufacturer is not required to inform surgeons that a particular construct is an off-label use).

Second, Mr. Pellerite asserts that Smith & Nephew engaged in unlawful off-label promotion of the BHR-THA and R3-THA constructs based on his characterization of hearsay documents and other witnesses' deposition testimony. In particular, Mr. Pellerite asserts that Smith & Nephew promoted a so-called bailout method whereby, "during a resurfacing surgery, after the BHR cup was placed …, the surgeon could leave the BHR resurfacing cup implanted and convert to a THA using the Smith & Nephew MFH." Pellerite Report (Ex. F) at 6; *see also id.* at 8 ("Smith & Nephew trained surgeons on the bailout procedure."). The only evidence of such

training that Mr. Pellerite cites, however, is a single surgeon's "recollection … 13, 14 years ago" that "something was brought up" where an unidentified person in an unidentified setting "pitch[ed]" the BHR-THA "as a bailout" option. *Id.* at 6–7. Mr. Pellerite admitted at his deposition that he is aware of no evidence that Smith & Nephew ever promoted the BHR-THA or R3-THA as a "bailout method" besides this one equivocal and vague statement, Pellerite Dep. (Ex. G) at 174–76.

Next, Mr. Pellerite alleges that Smith & Nephew's use of "color-coded packing" represented "the most blatant effort by S&N to market the unapproved/off-label use." Pellerite Report (Ex. F) at 8–9. This testimony misunderstands the purpose and function of this color coding. As explained by other fact witnesses not considered by Mr. Pellerite, Smith & Nephew used color coding within the BHR system to ensure that surgeons used the right-sized components. *See, e.g.*, BHR Post-Market Surveillance Report (May 19, 2016) [SN_BHR_MDL_03369990] (Ex. H) at 4; Weymann Dep. (Ex. E) at 40–42. As for the MFH, Smith & Nephew provided surgeons with color-coded trial heads so surgeon could confirm that a particular component size would fit appropriately within the patient's natural acetabulum before opening the box (and thus requiring the MFH to be used or discarded) or implanting the wrong size into the patient. *See, e.g.*, Deposition of Jason B. Sells (Feb. 28, 2019) ("Sells Dep.) (Ex. I) at 82–84; Modular Head Hemi-Arthroplasty System—Assembly Instructions (Sept. 2006) [SN_BHR_MDL_1555243] (Ex. J), at 3. These color coding systems were a reasonable way for Smith & Nephew to reinforce the components' approved uses. *See* West Report (Ex. A) at 95–98. Mr. Pellerite admitted at his deposition that he was unaware of these uses for the color coding and that he had not seen any Smith & Nephew materials describing color coding as a method for matching the MFH with BHR components. *See* Pellerite Dep. (Ex. G) at 213–17.

Finally, Mr. Pellerite says that Smith & Nephew promoted the BHR-THA and R3-THA because some sales representatives would have a MFH available should a surgeon request one during a resurfacing procedure. Pellerite Report (Ex. F) at 11–12. Mr. Pellerite admitted, however, that manufacturer representatives *can* provide surgeons with components for "off-label" uses upon request. *See* Pellerite Dep. (Ex. G) at 61. Mr. Pellerite states that sales representatives "would offer" a MFH as a method for converting to a THA. However, he does not provide any evidence that "offers" occurred, nor does he explain whether he meant that representatives would affirmatively suggest using the BHR in a THA or if they would simply offer the component in response to an unsolicited request from a surgeon. Pellerite Rep. (Ex. F) at 11–12[4]

Third, Mr. Pellerite opines that Smith & Nephew "had a duty" to inform surgeons using the BHR-THA that Smith & Nephew had withdrawn the BHR-THA in non-U.S. markets and to take other steps, including recalling the MFH in the U.S., changing the labeling to include contraindications against a BHR-THA construct, and requiring representatives to affirmatively warn surgeons not to use the off-label BHR-THA construct. *Id.* at 13.

LEGAL STANDARD

Under Rule 702, the federal courts "act as gatekeepers to 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.'" *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 588 (1993)). That gate-keeping responsibility is critically important because, "due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'" *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (quoting *Daubert*, 509 U.S.

[4] Mr. Pellerite also contends that an internal document constituted off-label marketing of the R3 in a metal-on-metal THA construct, but at his deposition he admitted that he was unaware that the document actually showed a R3 with a *poly* liner, which was indicated for use in a THA procedure. *See* Pellerite Dep. (Ex. G) at 114–15, 259.

at 595). Thus, the Court must "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Cooper*, 259 F.3d at 203 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). Rule 702 sets out a framework for carrying out the Court's gatekeeping responsibility, and dictates that a "witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise" but only "if" four additional conditions are met. Fed. R. Evid. 702.

First, the opinion must "help the trier of fact to understand the evidence or to determine a fact in issue." *Id.*; *Cooper*, 259 F.3d at 199 n.1. As part of its "gate-keeping function," the Court must determine whether scientific evidence, even if it were reliable, "appl[ies] to the facts in the individual case under consideration." *Newman* v. *Motorola, Inc.*, 218 F. Supp. 2d 769, 772 (D. Md. 2002), *aff'd* 78 F. App'x 292 (4th Cir. 2003). The question whether such testimony "will help the trier of fact . . . is generally a question of relevance or 'fit.'" *Id.*; *see also Allen v. Bank of Am., NA*, 933 F. Supp. 2d 716, 734 (D. Md. 2013) (excluding expert testimony that would not help determine a fact in issue); *Nease* v. *Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) ("Relevant evidence, of course, is evidence that helps 'the trier of fact to understand the evidence or to determine a fact in issue."). *Second*, the testimony must be "based on sufficient facts or data." Fed. R. Evid. 702(b); *see Cooper*, 259 F.3d at 199 n.1. *Third*, the testimony must be "the product of reliable principles or methods." Fed. R. Evid. 702(c); *see Cooper*, 259 F.3d at 199 n.1. *Fourth*, the court must determine whether "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(d); *Cooper*, 259 F.3d at 199 n.1.[5]

[5] Matters that "bear on a judge's determination of the reliability of an expert's testimony . . . include: (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential

As to each of these elements, "[t]he proponent of [expert] testimony must establish its admissibility by a preponderance of proof." *Id.* at 199 (citing *Daubert*, 509 U.S. at 592 n.10).

ARGUMENT

I. MR. PELLERITE'S OPINIONS AS TO PREEMPTED CLAIMS ARE INADMISSIBLE.

Mr. Pellerite's opinion testimony concerning claims and theories preempted by federal law is inadmissible under Rule 702. *See* Memorandum (Mar. 1, 2021) [D.E. 2501] at 3–18. Such testimony is not relevant to any claim at issue, and its admission would mislead and confuse the jury, causing unfair prejudice and a waste of both the parties' and the Court's time. *See* Fed. R. Evid. 702(a), 403; *see, e.g.*, *Newman*, 218 F. Supp. 2d at 772 (opinions must "apply to the facts in the individual case under consideration"); *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1150 (D. Minn. 2011) (opinion inadmissible where "it is not relevant to any of [Plaintiff's] claims"); *In re Lipitor (Atovastatin Calcium) Mktg., Sales Practices and Prods. Liab. Litig.,* MDL No. 2:14-mn-02502-RMG, 2016 WL 2940778, at *3 (D.S.C. May 26, 2006) (ruling that expert's opinion concerning a preempted claim was "irrelevant" and "would be confusing and misleading to the jury").

A. Mr. Pellerite's Opinion that the BHR Cup and R3 Liner Were Not Legally Marketed Is Preempted.

The crux of Mr. Pellerite's report is his opinion that a physician's use of BHR cup or the R3 metal liner, not as part of a complete BHR system, renders the BHR cup or R3 liner itself (and any construct in which it is used) an unapproved device. *See, e.g.*, Pellerite Report (Ex. F) at 6 ("[W]hen the BHR cup was used in a THA it was an *unapproved use* and not an *off-label use*.").

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rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Cooper*, 259 F.3d at 199 (citing *Daubert*, 509 U.S. at 592-94).

Based on that opinion, Mr. Pellerite concludes that Smith & Nephew failed to warn surgeons of the supposed regulatory nature of the BHR-THA or R3-THA and that Smith & Nephew was engaged in promotion of unapproved devices. As explained below, Mr. Pellerite is wrong as a matter of law and, even if he were qualified to offer them, his legal conclusions would therefore be unhelpful to the jury. In addition, Mr. Pellerite's opinions about the regulatory status of the BHR cup and R3 liner—and the steps Smith & Nephew should have taken to bring those components into what he views as compliance—are expressly and impliedly preempted by federal law.

As the Court has already ruled, the FDA has approved the BHR system and all components making up the BHR system. *See THA Preemption Ruling*, 401 F. Supp. 3d at 551–52; *see also Judge Rotenberg Ed. Ctr., Inc. v. FDA*, No. 20-1087, --- F. 4th ---, 2021 WL 2799891, at *4 (D.C. Cir. July 6, 2021) ("The [FDCA] does not suggest, not should we read into it, a limitation that the device must be marketed for the particular use for which the practitioner wants to utilize the device."). The BHR-THA and R3-THA are not, as Mr. Pellerite contends, unapproved devices, but rather are "hybrid systems that are comprised of both premarket-approved and § 510(k)-approved components." *THA Preemption Ruling*, 401 F. Supp. 3d at 546. Mr. Pellerite's opinions that "the BHR and R3 components at issue in this matter were not legally marketed" or that Smith & Nephew should have sought additional regulatory clearances, such as seeking an investigational device exemption ("IDE") are thus preempted because they would impose obligations different from or in addition to the BHR's and R3's PMA. *See, e.g.*, Pellerite Report (Ex. F) at 5, 8–9.

These opinions are an attack on PMA components themselves, and are therefore preempted under the Court's *THA Preemption Ruling*. *See* 401 F. Supp. 3d at 555 ("[T]he court concludes that § 360k(a) preempts non-parallel state-law claims that target premarket-approved

components"). According to Mr. Pellerite, Smith & Nephew was required to take some actions to prevent the BHR cup and R3 metal liner from being used by surgeons in an unapproved manner. *See* Pellerite Report (Ex. F) at 5–8. The MFH is irrelevant to these opinions; it was physicians' use of the BHR cup or R3 metal liner without the BHR resurfacing head (not their use *with* the MFH) that, in Mr. Pellerite's opinion, rendered this use unapproved and improperly marketed, regardless of whether those components were used with the MFH, something else, or nothing at all. *See id.* at 5–6.[6] While Mr. Pellerite is not clear what, exactly, Smith & Nephew could or should have done based on surgeons' individual decisions to use these PMA components in an off-label manner, any requirement—a warning label, a training obligation, a restriction on sale, etc.—would impose new, non-federal obligations on these FDA-approved components themselves. Any such requirement would involve, at its core, a PMA-approved component, and therefore would be preempted.

In addition, Mr. Pellerite's opinions that the BHR and R3 metal liner "were not legally marketed" because physicians used them in off-label constructs and that physician's use of the BHR-THA or R3-THA "did not qualify for the Practice of Medicine exemption" is impliedly preempted because it seeks to enforce a view of applicable law that conflicts directly with the structure of the FDCA. *See* Pellerite Report (Ex. F) at 5, 8. The FDA has determined that PMA components remain PMA-approved even when used in combination with non-PMA devices. *See* Amicus Br. of FDA, *Shuker v. Smith & Nephew, Inc.*, No. 16-3785, 2017 WL 4151264 (3d Cir. Sept. 14, 2017) at *10, *Shuker,* 885 F.3d at 773. Mr. Pellerite cannot second guess that judgment

[6] In fact, Mr. Pellerite's opinions would impose obligations on the BHR system as a whole—namely, an obligation to prevent surgeons from using components of the BHR other than as part of a complete BHR system. *See* Pellerite Report (Ex. F) at 5 ("Only when all of the components are used together is the device considered by FDA to be approved (cleared).").

and opine that, in fact, PMA-approved components become unapproved devices that cannot exist on the market when they are used in combination with non-PMA components. Such an argument would effectively give Plaintiffs a private right to enforce the FDCA. *See Buckman*, 531 U.S. at 348, 350.

Further, Mr. Pellerite's opinion that a component is approved only when it is used as indicated in an approved system would insert FDA into the regulation of the practice of medicine, which Congress has directed FDA may not do. *Id.* at 350-51 ("[T]he FDCA expressly disclaims any intent to directly regulate the practice of medicine") (citing 21 U.S.C. § 396). As the D.C. Circuit recently held, the FDA lacks authority to approve a device for certain indications and outlaw their use in others. *See Judge Rotenberg Ed. Ctr.,* 2021 WL 2799891, at *4–5. Rather, once the FDA approves a device, Congress has left to state and state medical licensing boards the sole authority to regulate where and how those devices can be used. *Id.* at *6. (discussing federalism concerns addressed by practice-of-medicine statute). Mr. Pellerite's opinion that the BHR cup or the R3 metal liner can be used by surgeons only in some procedures is therefore impliedly preempted (and this inadmissible) because it would upset the congressionally mandated balance between FDA's and states' regulatory authority.

B. Mr. Pellerite's Opinion that Smith & Nephew Should Have Trained Physicians Regarding the BHR-THA or R3-THA Is Preempted.

In its *THA Preemption Ruling*, the Court held that "any claims that Smith & Nephew had a duty to train physicians as to the BHR-THA and R3-THA systems are preempted," because there is no "federal requirement that mandates manufacturers train physicians as to off-label uses." 401 F. Supp. 3d at 563. Despite this, Mr. Pellerite opines that Smith & Nephew did not adequately train surgeons on the use (or non-use) of the BHR-THA or R3-THA. *See, e.g.*, Pellerite Report (Ex. F) at 6 ("S&N never advised surgeons that it did not have FDA approval for the resurfacing

cup to be used in a THA, and that this 'bailout' device was an unapproved device."); *id.* at 10 ("[Surgeons] rely on the firm's training …."); Pellerite Dep. (Ex. G) at 198 ("[FDA] require[s] surgeons' training … for them to use the device in a way to assure that it's going to be used as intended and appropriately.").

As this Court and others have repeatedly held, the MDA expressly preempts a failure to train claim that imposes "'substantive requirements' different from or inconsistent with the federal law." *Gomez v. St. Jude Med. Diag. Div. Inc.*, 442 F.3d 919, 929 (5th Cir. 2006); *accord, e.g.*, *THA Preemption Ruling*, 401 F. Supp. 3d at 563; *Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485, 493 (W.D.N.C. 2017). Federal law does not impose any obligation to train physicians on the off-label use of an approved or cleared medical device. *THA Preemption Ruling*, 401 F. Supp. 3d at 563. If credited, Mr. Pellerite's theory that Smith & Nephew should have trained surgeons on the proper use of the BHR would impose additional, non-federal obligations on Smith & Nephew. *See* West Report (Ex. A) at 39. In addition, even if federal law did impose a duty on Smith & Nephew to train physicians on the off-label use of BHR or R3 components, that duty would exist only as a matter of federal law and would therefore be impliedly preempted. *See Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1329–30 (11th Cir. 2017). Mr. Pellerite's failure to train opinions are therefore inadmissible.

C. Mr. Pellerite's Opinion that Smith & Nephew Should Have Warned Physicians that the BHR-THA or R3-THA Was "Off-Label" Is Preempted.

For many of the same reasons that Mr. Pellerite's failure to train opinions are preempted, federal law also preempts his opinions that Smith & Nephew should have "warn[ed] surgeons that the BHR-THA and the R3-THA were unapproved devices," "that the BHR-THA and R3-THA involved any off-label usage," and of unspecified "risks" of using the BHR-THA or R3-THA as a construct. *See* Pellerite Report (Ex. F) at 8–9; *see also id.* at 13 (opining Smith & Nephew had a

duty to inform surgeons of foreign market withdrawals of the BHR-THA); *id.* at 14 ("Smith & Nephew failed to act as a reasonably prudent company … through its failure to warn surgeons of the risks of the unapproved devices, failing to warn surgeons of the risks of using the BHR cup, the MFH and the R3 metal liner off-label, and failing to warn surgeons that the BHR-THA was denied approval.").

Just as the Court has ruled that federal law imposes no duty to train physicians, *THA Preemption Ruling*, 401 F. Supp. 3d at 563, Mr. Pellerite admitted that there is no federal duty to warn physicians of the regulatory status of a hybrid construct such as the BHR-THA or R3-THA. *See* Pellerite Dep. (Ex. G) at 262–66. In fact, if Smith & Nephew were to have unsolicited conversations with physicians about the regulatory status of the BHR-THA or R3-THA, Mr. Pellerite testified that such conversations could be viewed as illegal off-label promotion. *See id.* at 105–06 ("bringing up unapproved uses, indications without prompt would be off-label promotion"; "It would be promoting an off-label use, that's correct"); *accord* Deposition of David L. West, Ph.D., MPH (May 25, 2021) ("West Dep.") (Ex. K) at 63–64 (advising surgeons, without prompting, that "the MFH coupled with the BHR cup is not an approved device" would be "in a left-handed way … promoting an off-label use"). Mr. Pellerite's "heads-I-win, tails-you lose" opinion that Smith & Nephew is liable for failure to warn physicians of the regulatory status of a hybrid construct and at the same time that Smith & Nephew also would be liable if it did warn them demonstrates the nonsensical nature of his opinions.

Moreover, Mr. Pellerite's opinion that Smith & Nephew should have affirmatively advised surgeons of the regulatory status of the BHR-THA and R3-THA, notwithstanding what he believes is a prohibition on doing so, is expressly preempted by federal law. Although the Court has observed that federal law does not impose any affirmative obligations on the BHR-THA or R3-

THA, *see THA Preemption Ruling*, 401 F. Supp. 3d at 556, federal law *does* prohibit Smith & Nephew from promoting off-label uses. Mr. Pellerite's opinion that Smith & Nephew should have affirmatively advised surgeons of the regulatory status and purported risks associated with the BHR-THA or R3-THA, without any prompting or inquiry from the physician, would impose an obligation diametrically opposed to that federal requirement by forcing Smith & Nephew to engage in something that, Mr. Pellerite and Dr. West both agree, potentially could be seen as off-label promotion.

In addition, Mr. Pellerite's opinions that Smith & Nephew had a duty to insert itself into the practice of medicine is impliedly preempted. As noted, Congress and FDA have determined, as a matter of long-standing federal policy, that the practice of medicine should be left to the discretion of physicians and state medical licensing bodies, not manufacturers and the FDA. *See* 21 U.S.C. § 396; *Judge Rotenberg Ed. Ctr., Inc.*, --- F. 4th ---, 2021 WL 2799891, at *4 ("Section 396 ensures that once the FDA permits a device to be marketed for one use, health care practitioners have the flexibility to draw on their expertise to prescribe or administer the device for any condition or disease, not just the use the FDA approved—in short, to practice medicine"). Mr. Pellerite's report, however, concludes that Smith & Nephew had a duty to insert itself into the practice of medicine and effectively prohibit the use of a BHR cup or R3 metal liner in a THA procedure by warning physicians not to perform an off-label procedure (regardless of the surgeon's professional judgment), refusing to provide the MFH to surgeons who request it during a BHR procedure, and taking unspecified "other reasonable steps to ensure patient safety." Pellerite Report (Ex. F) at 13. Such an expansion of the role of device makers and device regulation into the practice of medicine is preempted because it "conflicts with" the FDCA's statute preventing FDA from regulating the practice-of-medicine and therefore "stands as an obstacle to" Congress'

design for allocating regulatory authority in the medical device sphere. *See In re BHR I*, 300 F. Supp. 3d at 741–42.

D. Mr. Pellerite's Opinion Concerning the BHR's Label Is Preempted.

Finally, Mr. Pellerite's opinions concerning the labeling of the BHR or its components is preempted and therefore inadmissible. The Court has ruled that "[c]laims alleging that Smith & Nephew was obligated to amend its labeling of the BHR cup and R3 metal liner are expressly preempted by the MDA because they would impose additional, broader requirements on premarket-approved devices." *THA Preemption Ruling*, 401 F. Supp. 3d at 562. Nonetheless, Mr. Pellerite's opinions criticize the content and utility of the labeling of the BHR-THA and R3-THA components, including the BHR cup and R3 metal liner. *See, e.g.*, Pellerite Report (Ex. F) at 10 ("It is well established that surgeons do not rely on the in-box labeling or instructions for use ….").

In particular, Mr. Pellerite attacks the color coding on the BHR cup that parallels the corresponding-sized MFH. *See id.* at 9–10. This color-coding, Mr. Pellerite admits, "is part of the labeling." Pellerite Dep. (Ex. G) at 204; *see* 21 U.S.C. § 321(m) (defining "labeling" to mean "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article"). According to Mr. Pellerite, Smith & Nephew should have changed the color coding on the BHR component so it would not match the color coding on an equivalent MFH. *See, e.g.*, *id.* at 205 ("*Resurfacing components should have been one color*, and THA components should have been another color ….") (emphasis added).[7] This opinion

[7] As noted earlier, Smith & Nephew used color coding within the BHR system to ensure that surgeons used the right-sized components. *See, e.g.*, BHR Post-Market Surveillance Report (May 19, 2016) [SN_BHR_MDL_03369990] (Ex. H) at 4; Weymann Dep. (Ex. E) at 40–42. As for the MFH, Smith & Nephew provided surgeons with color-coded trial heads so surgeon could confirm that a particular component size would fit appropriately within the patient's natural acetabulum before opening the box (and thus requiring the MFH to be used or discarded) or implanting the wrong size into the patient. *See, e.g.*, Sells Dep. (Ex. I) at 82–84; Modular Head Hemi-

would impose an additional, non-federal requirement on the BHR component itself—namely, that whatever color is used on the BHR must be different from the color coding on the MFH. These opinions are directed to PMA component labeling and are therefore preempted, in addition to being unreliable, as discussed below.

II. MR. PELLERITE'S OPINIONS THAT ARE NOT THE PRODUCT OF RELIABLE METHODS ARE INADMISSIBLE UNDER RULE 702.

Many of Mr. Pellerite's opinions fail for other reasons as well. In particular, before a purported expert may testify at trial, the proponent of the expert testimony must demonstrate that the expert's opinions are within his area of expertise and are the product of reliable methods applied to the facts of the case. Fed. R. Evid. 702; *see, e.g.*, *Cooper*, 259 F.3d at 203. Under *Daubert*, courts assume a gatekeeping role to ensure that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152. That gate-keeping responsibility is necessary because, "due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'" *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 595). Mr. Pellerite falls short of these standards in several critical respects.

A. Mr. Pellerite's Characterization of the BHR-THA and R3-THA as Unapproved Devices Is Baseless and Unhelpful Legal Opinion That He is Unqualified to Offer.

As discussed above, *supra* § I.A, the crux of Mr. Pellerite's opinions is that the BHR-THA and R3-THA were not, as this Court has previously held, off-label configurations of approved and cleared components, but rather were unapproved devices. *Compare* Pellerite Report (Ex. F) at 5–8, *with THA Preemption Ruling*, 401 F. Supp. 3d at 551–52. This is incorrect as a matter of law,

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Arthroplasty System—Assembly Instructions (Sept. 2006) [SN_THA_MDL_0007746] (Ex. J), at 3.

as the Court has ruled. *Id.* As a non-lawyer, Mr. Pellerite is unqualified to offer these opinions. Further, his opinions are inadmissible because they are unreliable and unhelpful.

Mr. Pellerite is not qualified, having no legal training, to instruct the jury on FDA law. In addition, Mr. Pellerite's opinion that the BHR-THA or R3-THA were unapproved devices or that physicians' use of those constructs is not an off-label use also is inadmissible because such opinions would not be helpful to the jury. *See* Fed. R. Evid. 702(a). Expert opinions that merely recite "a legal standard or draw[] a legal conclusion by applying law to the facts [are] generally inadmissible." *United States v. McIver*, 470 F.3d 550, 561-62 (4th Cir. 2006); *accord* Memorandum (Mar. 1, 2021) [D.E. 2501] ("BHR Track *Daubert* Ruling") at 26; *United States v. Walker-Bey*, 800 F. App'x 161, 165 (4th Cir. 2020) ("[A]n expert generally is not permitted to apply law to facts to reach a legal conclusion, as such testimony is not considered helpful to the jury."). An expert's testimony is an impermissible legal conclusion when "the terms used by the witness have a separate, distinct and specialized meaning in the law from that in the vernacular." *JFJ Toys, Inc. v. Sears Holdings Corp.*, 237 F. Supp. 3d 311, 324 (D. Md. 2017). Court therefore will exclude portions of expert reports that offer "unhelpful legal conclusions." *Sprint Nextel Corp. v. Simple Cell, Inc.*, No. CCB-13-617, 2016 WL 524279, at *5 (D. Md. Feb. 10, 2016).

Mr. Pellerite's opinions that the BHR-THA and R3-THA are unapproved devices and that the use of those constructs is an unapproved use are improper and unhelpful legal conclusions. To reach those conclusions, Mr. Pellerite applies his understanding of the facts to his understanding of governing FDA law and regulations. *See, e.g.*, Pellerite Report (Ex. F) at 8 ("The BHR-THA was not legally on the market, and did not qualify for the Practice of Medicine exemption found in Section 1006 of the FD&C Act because it was not off-label use of an approved device for another indication or reason."). Mr. Pellerite's use of terms like "unapproved" and "practice of medicine"

that have "considerable legal baggage" are improper legal opinions that "invade[] the province of the jury." *United States v. Perkins*, 470 F.3d 150, 158 (4th Cir. 2006).[8] Indeed, these opinions usurp both the role of the Court, which will instruct the jury on the law at trial, and the role of the jury, which will be capable of applying the facts of the case to the law as explained by the Court.

Moreover, even if Mr. Pellerite's legal conclusions could be helpful, they are flatly incorrect, and permitting him to offer these opinions at trial would necessarily confuse and mislead the jury. This Court and others have consistently ruled that components of PMA devices are themselves approved, and that the use of an approved component with a cleared component in a hybrid system is a legal (even "implicitly encourage[d]") off-label use. *See THA Preemption Ruling*, 401 F. Supp. 3d at 551–553; *Shuker v. Smith & Nephew PLC*, 2015 WL 1475368, at *3, 9 (E.D. Pa. 2015) (finding that use of the R3 metal liner in a THA procedure is "an off-label use"); *Hawkins v. Medtronic, Inc.*, No. 13–499, 2014 WL 346622, at *5 (E.D. Cal. Jan. 30, 2014) ("Use of the INFUSEO Bone Graft Component without the LT–Cage is simply an off-label use of the device."); *see also Judge Rotenberg Ed. Ctr.*, 2021 WL 2799891, at *4 (holding FDCA does not authorize FDA to approve a device for some procedures but not others). Mr. Pellerite, by contrast, was unable to point to any authority or fact in evidence to support his position that "when the BHR cup was used in a THA it was an *unapproved use* and not an *off-label* use." Pellerite Report (Ex. F) at 6. Indeed, he admitted that this terminology is not something he came up with and that he was not aware of any Smith & Nephew documents or personnel discussing the BHR-THA or R3-

[8] Mr. Pellerite's description of the practice of medicine statute as an "exemption" is also misleading. The practice of medicine is entirely outside of the FDA's regulatory domain. *See* 21 U.S.C. § 396. Accordingly, describing the practice of medicine statute as an "exemption" does not accurately reflect the statute itself or the overall regulatory structure. *See* West Report (Ex. A) at 93, 97 ("And the practice of medicine, being outside the domain of FDA authority, does not constitute an exemption of any FDA requirements."); *cf., e.g.*, 21 U.S.C. § 360j(b) (exempting custom devices from certain provisions of the MDA).

THA as a system. *See* Pellerite Dep. (Ex. G) at 110–12; *see also* West Dep. (Ex. K) at 159 ("Q. Have you ever— in your decades of experience with FDA or as an FDA consultant, have you ever heard someone refer to a combination of different devices approved or cleared separately as a medical device? A. No.").

Plaintiffs' counsel has taken the position that whether the BHR-THA and R3-THA are off-label uses or unapproved devices is something to "let the jury sort out." *Id.* at 90. But there is nothing for the jury to sort out. *See id.* at 161–63. Mr. Pellerite's opinion lacks any legal or factual foundation such that its submission to the jury would only confuse the jury or (at best) waste the jury's and the Court's time. *See, e.g.*, *Berlyn, Inc. v. The Gazette Newspapers, Inc.*, 214 F. Supp. 2d 536 (D. Md. 2002) ("Even if a witness is qualified to offer an expert opinion, that opinion can be excluded if it is based on inadequate facts or flawed methodology."). Mr. Pellerite's novel, baseless, and unhelpful theory that the BHR-THA and R3-THA were unapproved devices is therefore inadmissible under Rule 702.

B. Mr. Pellerite's Conclusion that Smith & Nephew Engaged in Off-Label Promotion Is Unreliable and Would Be Unhelpful to the Jury.

Rule 702 also precludes Mr. Pellerite from summarizing to the jury deposition transcripts and documents that, he contends, constitute off-label promotion for several reasons. *See* Pellerite Report (Ex. F) at 5–13.

First, determining whether certain facts support a conclusion of off-label promotion is a job for the jury, not a paid expert. *See, e.g.*, *Perkins*, 470 F.3d at 158–59. Mr. Pellerite's opinion, therefore, that certain events constitute off-label promotion is an unhelpful and improper legal opinion. *See supra* § II.A.

Second, Mr. Pellerite may not offer the jury his summary and commentary on the testimony of other witnesses or the import of certain documents. Expert testimony requires "specialized

knowledge." Fed. R. Evid. 702(a). A narrative summarizing documents, by contrast, invades the province of the jury, amounts to mere advocacy on plaintiff's behalf, and thus falls outside the scope of what Rule 702 permits. *See In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1337 (S.D. Fla. 2010) (holding that expert's opinions are improper because they "consist of a narrative of selected regulatory events and a summary of [defendant's] internal documents"); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008) (noting that documents are "just as easily summarized by a jury"), *aff'd in relevant part*, 586 F.3d 547 (8th Cir. 2009). Mr. Pellerite has no specialized expertise that allows him to speak for the witnesses who have been deposed in this case. Those witnesses can speak for themselves at trial, and the jury can draw its own conclusions. The same analysis applies to the documents that Mr. Pellerite purports to summarize: if those documents are admissible, they "should be presented to the jury directly." *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009).

Third, Mr. Pellerite's opinions are not "the product of reliable principles and methods." Fed. R. Evid. 702(c). Mr. Pellerite is testifying as an FDA regulatory expert based on his experience with how the FDA monitors manufacturer promotions and enforces the prohibition on off-label promotion. *See* Pellerite Report (Ex. F) at 1. The FDA does not, however, police off-label promotion by reviewing snippets of transcripts and internal documents, in part because such ad hoc review can make it impossible to distinguish between doctor-initiated conversations about off-label uses and unprompted and unsolicited off-label promotion. Rather, the FDA conducts market surveillance through more formal and systematic methods, such as review advertisements, monitoring company websites, visiting manufacturers' exhibit booths at conferences, and investigating formal complaints. *See, e.g.*, West Report (Ex. A) at 57–58, 75. Mr. Pellerite does not base his opinions on any of these methods. *See id.* at 70–75 (finding no evidence that the FDA

ever issued a warning letter concerning off-label promotion of the BHR or MFH). Instead, he relies on his own subjective and often times implausible or incomplete reading of documents that would not be relevant to the FDA's investigation of possible off-label promotion. This is not consistent with the "level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

Finally, Mr. Pellerite's characterization of deposition transcripts and record documents as definitively showing off-label promotion should be excluded because many of his conclusions are baseless and providing them with the imprimatur of an expert is likely to mislead the jury and result in unfair prejudice to Smith & Nephew. For example, Mr. Pellerite states that Smith & Nephew "promoted" and "trained" surgeons on the BHR-THA as a "bailout" method. *See* Pellerite Report (Ex. F) at 6, 8; *supra* at 9–10. However, the only evidence Mr. Pellerite cites in his report of off-label promotion is equivocal testimony from an implanting physician, Dr. Valadie, that his "recollection" of a conversation "13, 14 years ago" was that the bailout "was something that was brought up." *Id.* at 6–7. At his deposition, Mr. Pellerite admitted that he had no other evidence that Smith & Nephew promoted the bailout method to surgeons or trained surgeons to perform the bailout method, and further admitted that Dr. Valadie never actually testified that his "recollection" of the bailout being "brought up" was part of his training. *See* Pellerite Dep. (Ex. G) at 168–71, 174–76.

Mr. Pellerite also places great weight on Smith & Nephew's use of color coding and Chart-Stiks as what he called the "most blatant effort by S&N to market the unapproved/off-label use." Pellerite Report (Ex. F) at 9–10. Yet, as described above, *supra* at 10, the color coding was in fact a way for surgeons to confirm that the proper *BHR components* were used together in a hip resurfacing and that the proper-size MFH was selected in a arthroplasty. Mr. Pellerite admitted

that he was unaware of the evidence explaining the reasons for use for the color coding, *see supra* at 10, and that he had not seen any documents from Smith & Nephew suggesting the color coding was used for the reasons he suggests. *See* Pellerite Dep. (Ex. G) at 213–17.

Given the lack of foundation and consideration underlying these opinions, they are inadmissible under Rule 702(a) and Rule 403. To the extent these documents and testimony are admissible directly, Plaintiffs may present them, if admissible, to the jury at trial. There is little, if any, marginal probative value to Mr. Pellerite providing his secondhand commentary on this evidence, but there is great risk that Mr. Pellerite's pronouncement that these documents demonstrate off-label promotion would invade the role of the jury and result in unfair prejudice that invades the jury's independent consideration of the evidence.

C. Evidence of Foreign Business and Regulatory Actions Is Irrelevant and Likely to Confuse the Jury.

Mr. Pellerite also offers opinions based on his understanding of Smith & Nephew's business and regulatory actions in other countries. *See, e.g.*, Pellerite Report (Ex. F) at 13. Mr. Pellerite is not in any sense an expert with regard to foreign business or regulatory matters. His experience working for FDA in the United States does not qualify him to testify as an expert concerning regulatory matters in other countries subject to different regulatory regimes or foreign business decisions. Further, the actions Smith & Nephew took in other countries are irrelevant to this case because they were made either for business reasons that have no bearing in this case or for regulatory reasons based on other countries' legal requirements. Such actions, courts have consistently held, are irrelevant, confusing, and a waste of time in cases concerning only domestic sale and marketing of a medical device. *See, e.g.*, *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 488 n.87 (S.D.N.Y. 2016); *In re Xarelto (Rivaroxaban) Prod s. Liab. Litig.*, No. 14-

2720, 2017 WL 4168410, at *3 (E.D. La. Sept. 20, 2017), *appeal docketed,* No. 17-30845 (5th Cir. Oct. 19, 2017).

In its Memorandum addressing Smith & Nephew's motions in limine in the *Redick* and *Mosca* cases, the Court ruled that evidence of foreign regulatory actions may be admissible for the limited purpose of proving notice. *See* Memorandum (June 11, 2021) [D.E. 2827] at 9–10. Mr. Pellerite, however, does not rely on this evidence simply to show notice; rather, he contends that Smith & Nephew had affirmative obligations in the U.S. market based on decisions made in other countries. *See, e.g.*, Pellerite Report (Ex. F) at 13 ("Smith & Nephew's failure to take any steps after this 2012 outside-US action was negligence."). Therefore, his discussion of these actions is inadmissible.

D. Mr. Pellerite's Opinions About Surgeons' Practice and Knowledge Are Unreliable and Outside His Expertise.

Finally, Mr. Pellerite lacks the expertise to discuss what surgeons do in the operating room, what information surgeons do or do not rely upon, or what surgeons knew or did not know at the time they performed a BHR-THA. Mr. Pellerite is not a medical doctor, or a doctor of any kind. *See id.* at 1. He has no expertise in the practice of medicine and no specialized knowledge in how orthopedic surgeons approach surgical procedures. Rather, the only relevant experience Mr. Pellerite offers is from his years as an FDA employee and consultant, and Congress has dictated that the FDA has no role in regulating surgeons or the practice of medicine.[9]

Despite this lack of relevant experience, Mr. Pellerite opines that surgeons "do not rely on the in-box labeling or instructions for use" and that they instead "rely on the firm's training, the

[9] At his deposition, Mr. Pellerite suggested that he is qualified to opine on surgical practice because "my wife was an operating room nurse" and "I've been around surgeons." Pellerite Dep. (Ex. G) at 193. There is no such thing, however, as expertise by association. That Mr. Pellerite knows individuals who may have relevant expertise does not make him an expert, and he did not identify that second-hand experience in his report as a basis for his opinions.

sales representatives …, and the label on the component that is actually in the operating room." *Id.* at 9–10; *see also, e.g.*, Pellerite Dep. (Ex. G) at 194 (instructions for use are "not present in the operating room" and the surgeon "is not the one that opens the device"). In fact, Mr. Pellerite even describes "what I believe standard of care is … for performing total hip or hip resurfacing." Pellerite Dep. (Ex. G) at 196. Mr. Pellerite, however, has no training or experience that would inform this opinion of what happens in an operating room or what is standard of care for orthopedic surgeons. His opinions on these topics are no more than lay speculation unsupported by any experience and unmoored from the facts of this litigation, and are therefore inadmissible. *See McCoy v. Biomet Orthopedics, LLC*, No. CV ELH-12-1436, 2021 WL 252556, at *20 (D. Md. Jan. 25, 2021) (excluding opinion that "most surgeons would not have read the IFU").

Mr. Pellerite also opines that "surgeons were not aware that the BHR-THA was denied approval by FDA," that "the BHR was not approved for use in a THA," or that "S&N considered the BHR-THA an off-label use of two different devices," or that the procedure they were performing "was off-label." *See* Pellerite Report (Ex. F) at 8, 9, 11. Mr. Pellerite has no basis to testify what all surgeons, most surgeons, or even a critical mass of surgeons knew about the BHR-THA or R3-THA. Rather, he bases this conclusion on his strained reading of what three surgeons testified to in this litigation. *See id.* at 8. This is not a reliable basis upon which to offer a broad opinion about *all* surgeons' knowledge or understanding about the regulatory status of the BHR-THA or R3-THA. The opinion should therefore be excluded.

CONCLUSION

For these reasons, the opinions of Mr. Pellerite are not appropriate expert testimony and are inadmissible under Federal Rules of Evidence 702 and 403.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Jana D. Wozniak, hereby certify that on this 12th day of July, 2021, I electronically filed the foregoing with the Court using the CM/ECF system, and thereby delivered the foregoing by electronic means to all counsel of record.

/s/ Jana D. Wozniak
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